HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –10336-02
October 3, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Yoon S. Kim, M.D.
Lead Interpreting Physician
Licking Memorial Women's Health
15 Messimer Dr.
Newark, OH 43055

Facility I.D.#: 215707

Dear Dr. Kim:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on September 27, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

Quality Assurance – Equipment - *Daily quality control tests* - 21 CFR 900.12(e)(1)(i)-(iii)

Your records revealed that your facility processed mammograms when the processor quality control parameters were out of limits for thirty-six days beginning on July 23 to September 27, 2001.

During the inspection, the inspector observed the daily processor quality control results; specifically the mid-density and the density difference values were outside of the allowable regulatory limits on July 23-27, 30 & 31, August 1 & 3, 6-9, 13-15, 17, 20-23, 27, 29-31, September 4, 11, 12, 18-21, 24-27, 2001. Your staff performed the crossover procedure in error by reestablishing the new mid-density and density difference baseline values using the old and the new operating levels instead of the correct calculated operating levels. When the inspector evaluated your facility's daily processor quality control records, using the new values given and compared these with the correct calculated baseline values, the processor mid-density & density difference values were not operating within plus or minus 0.15 of the correct baseline values.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

Also, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

Quality Assurance – *Equipment* - 21 CFR 900.12(e)(8)(i)&(ii)(A) as further required in 21 CFR 900.12 (e)(2)(iv)

Your records revealed that your facility failed to conduct proper corrective actions before further mammography examinations for density difference and mid density values found outside the regulatory limits.

As indicated in the previous paragraphs, the inspector observed your facility daily processor quality control results and found the mid-density and the density difference values were outside of the allowable regulatory limits beginning July 23 to September 27, 2001. As a corrective action, your facility performed a crossover procedure by using the incorrect mid density and density difference baseline values.

2. Personnel – *Interpreting Physicians* 21 CFR 900.12(a)(1)(ii)(A)

Your facility failed to produce documents demonstrating that [redacted]., an interpreting physician meets the continuing experience requirement of having interpreted or multi-read a minimum of 960 mammograms in a twenty-four month period.

During the inspection, the inspector observed your facility's personnel records and found that [redacted] had read a total of 866 mammography examinations in a twenty four month period prior to the date of the inspection.

The other items listed in your September 27, 2001 inspection report identified as Level 3 should also be corrected. We will verify corrections on these items during our next inspection. You are not required to address the Level 3 items in your written response.

Because these conditions may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, these represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

You must act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).
Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Mr. Keith Shipman
Division of Prevention
Bureau of Radiation Protection
Radiologic Technology Section
P.O Box 118
Columbus, Ohio 43266-0118

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/KShipman

Priscilla F. Butler, M.S.
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